

Exhibit 2



LEXSEE 2009 U.S. APP. LEXIS 25536

**IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE
LITIGATION; M. JOYCE HOWE, Plaintiff, Appellant, v. LEROY TOWNSEND,
Plaintiff, Appellee.**

No. 09-1196

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

2009 U.S. App. LEXIS 25536

November 19, 2009, Decided

SUBSEQUENT HISTORY: As Amended December 21, 2009.

PRIOR HISTORY: [*1]

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS. Hon. Patti B. Saris, U.S. District Judge.

Shepley v. Johnson & Johnson (In re Pharm. Indus. Average Wholesale Price Litig.), 582 F.3d 231, 2009 U.S. App. LEXIS 21214 (1st Cir. Mass., 2009)

COUNSEL: Donald E. Haviland with whom Michael J. Lorusso and The Haviland Law Firm, LLC were on brief for the appellant.

Steve Berman with whom Sean R. Matt, Thomas M. Sobol, Edward Notargiacomo, Hagens Berman Sobol Shapiro LLP, Kenneth R. Wexler, Jennifer Fountain Connolly, Wexler Wallace LLP, Jeffrey Kodroff, John A. Marcoretta, Spector, Roseman, Kodroff & Willis P.C., Marc H. Edelson, and Hoffman & Edelson were on brief for the appellee.

JUDGES: Before Lynch, Chief Judge, Torruella and Howard, Circuit Judges.

OPINION BY: LYNCH

OPINION

LYNCH, Chief Judge. One unhappy named plaintiff appeals from an order approving a \$ 24 million class action settlement in one multidistrict litigation, in which class members allege that AstraZeneca Pharmaceuticals LP (AstraZeneca) published artificially inflated prescription drug prices. *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456, Civ. A. No. 01-12257, 2008 U.S. Dist. LEXIS 111818 (D. Mass. Dec. 15, 2008) (order approving final settlement) (*In re Pharm. Final Settlement Approval*). The settlement is between AstraZeneca and a class of consumer plaintiffs who claimed they overpaid [*2] Medicare co-payments because AstraZeneca inflated the price of Zoladex.

M. Joyce Howe, one of the class representatives for the AstraZeneca consumer subclass, appeals. The other AstraZeneca subclass representative, Leroy Townsend, asks us to uphold the settlement. Howe argues that the settlement must be rejected on the grounds that it creates a cy pres fund of up to \$ 10 million rather than distributing all recovery to class members; that the settlement is not fair, reasonable, and adequate because its method for calculating and distributing class members' damages is flawed; and that the parties allegedly improperly negotiated fees simultaneously with the settlement. Howe failed to raise the last argument before final approval of the settlement.

Howe also argues to us two procedural objections she did not make in the district court. Howe contends the

district court's order approving the settlement, which expanded the settlement class, did not sufficiently define the new class and its claims as required by *Rule 23(c)(1)(B)*. Howe also argues that the district court did not properly reappoint class counsel under *Rule 23(g)*, *see Fed. R. Civ. P. 23(g)*, when approving the expanded settlement [*3] class.

The cy pres and *Rule 23(c)(1)(B)* issues are ones of first impression for this court. We find Howe's challenges meritless and affirm the district court, which handled this matter with great sensitivity and care.

I.

This appeal is in one case of a series of class actions alleging pharmaceutical companies fraudulently inflated a figure known as the "average wholesale price" (AWP) between 1991 and 2003 to boost sales.¹ This court has already decided other appeals from these multidistrict litigations and related cases. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 231 (1st Cir. 2009); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir. 2009); *Nat'l Ass'n of Chain Drug Stores v. New England Carpenters Benefits Fund*, 582 F.3d 30 (1st Cir. 2009); *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009).

¹ The AWP was supposed to reflect the average amount wholesalers charged providers for pharmaceutical drugs. Wholesalers bought drugs from manufacturers, marked up the price about 20 to 25 percent to make a profit, and resold them to physicians. Patients obtaining drugs from physicians either paid out of pocket or had their [*4] insurers reimburse physicians, while usually making a co-payment. Insurers and Medicare reimbursed physicians based on published AWPs, which in turn determined patients' co-payments.

Over time, the acquisition costs for physicians plummeted. Wholesalers added much smaller markups, around 2.5 percent, due to increasing competition. And pharmaceutical companies began using rebates and similar devices to further drive down the cost of drugs. Yet pharmaceutical companies did not adjust published AWPs to reflect this market change. Instead, companies continued to push costs down but reported AWPs based on the 20 to 25 percent markup.

Because Medicare and insurers continued to rely on published AWPs, the "spread" between physicians' acquisition costs and their reimbursements grew dramatically, generating increasing profits for doctors. Pharmaceutical companies marketed this spread to physicians to encourage doctors to prescribe the companies' drugs.

The healthcare industry treated the AWP, which pharmaceutical companies self-reported, as the sticker price for drugs. Insurers used AWPs to decide how much to reimburse providers when patients obtained drugs, which in turn affected patients' co-payments. [*5] Most of the drugs involved in these litigations are expensive drugs for serious illnesses, including cancer. The drug involved in this appeal, Zoladex, is commonly used to treat prostate cancer. Consequently, Medicare, insurers, and patients allegedly overpaid by many millions of dollars for critical treatments based on manipulated AWPs.

A coalition of citizen, healthcare, senior citizen, and consumer advocacy groups sued dozens of drug manufacturers and healthcare-product companies² in the District Court for the District of Massachusetts on December 19, 2001. Similar lawsuits were filed across the country, and on April 30, 2002, the Judicial Panel on Multidistrict Litigation consolidated the lawsuits and assigned the case to the District Court for the District of Massachusetts. *In re Immunex Corp. Average Wholesale Price Litig.*, 201 F. Supp. 2d 1378, 1379-81 (J.P.M.L. 2002).

² The complaint also named numerous co-conspirators and Doe defendants, possibly including other companies and doctors who participated in fraudulent billing.

The district court ultimately divided the multidistrict litigation into two tracks, a fast track (Track One) and a normal track (Track Two). Track One included [*6] three classes. One of the three--Class 1, called the Medicare Part B Co-Payment Class--consisted of patients covered by Medicare Part B who made co-payments for these drugs. A subclass of Class 1, which sued AstraZeneca for inflating the price of Zoladex, is involved in this appeal.

The Medicare Part B Co-Payment Class alleged that the defendants violated state consumer protection statutes

by artificially inflating AWPs. Between 1992 and 2005, Medicare Part B reimbursements were based on published AWPs under federal law.³ Medicare covered 80 percent of this cost, requiring patients to make a 20 percent co-payment.

3 Medicare reimbursed physicians 100 percent of the AWP from 1992 to 1998, up to 95 percent of the AWP until 2003, and 85 percent of the AWP until 2005, when the federal government finally stopped relying on AWPs altogether.

Most patients had supplemental insurance that covered some but not all of this co-payment. Those who had supplemental coverage for the full co-payment were excluded from the class. Most class members had Medigap insurance that covered 80 percent of the 20 percent co-payment (leaving patients to pay 20 percent of the 20 percent Medicare co-payment). Thus [*7] patients in the class were differently affected depending on whether they had supplemental insurance and how much of the co-payment that insurance covered.

On August 16, 2005, the district court denied some proposed classes and deferred certifying the Medicare Part B Co-Payment class until the plaintiffs located individuals to act as class representatives. *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 96 (D. Mass. 2005) (order partially denying and partially deferring class certification) (*In re Pharm. Preliminary Class Certification*).⁴ The court issued the order after carefully analyzing whether the Medicare Part B Co-Payment Class, as well as all proposed Track One classes, met the requirements for class certification under *Rule 23 of the Federal Rules of Civil Procedure*. *Id.* at 76-96. The plaintiffs filed an amended complaint in October 2005 that reflected the court's instructions.

4 The district court issued many orders in this case, only a handful of which are relevant to this appeal. We refer to orders based on their content for the purposes of this appeal only.

The district court certified the Medicare Part B Co-Payment Class under *Rule 23(b)(3) of the Federal Rules of Civil Procedure* [*8] on January 30, 2006. *In re Pharm. Indus. Average Wholesale Price Litig.*, 233 F.R.D. 229, 230-31 (D. Mass. 2006) (order granting and denying class certification) (*In re Pharm. Class Certification*). It defined the class as "[a]ll natural persons nationwide who made, or who incurred an obligation

enforceable at the time of judgment to make, a co-payment based on AWP for a Medicare Part B covered Subject Drug that was manufactured by" the defendants, including AstraZeneca, between January 1, 1991, and January 1, 2005. *Id.* at 229-32 (footnote omitted). The court excluded residents in nine states whose consumer-protection statutes did not create a cause of action, unlike the law in states whose residents were certified as class members. *Id.* at 230. It certified class counsel under *Rule 23(g)*. *Id.* at 232.

The court divided the plaintiffs into four subclasses according to which pharmaceutical-company defendant had distributed the subject drugs to them. *Id.* at 230. The court certified Howe⁵ and Townsend as subclass representatives for the class members suing AstraZeneca. *Id.*

5 The court certified Howe individually and on behalf of her husband's estate.

After months of intense litigation and negotiation, [*9] AstraZeneca and the Zoladex subclass reached a final settlement in May 2007, on the eve of trial.⁶ That settlement is at issue in this appeal. The plaintiffs' expert had calculated the class's damages were \$ 31,128,851. In the settlement, AstraZeneca agreed to pay \$ 24 million in total compensation to all class members or, for deceased class members, to their spouses or the legal representatives of their estates. In an effort to achieve a comprehensive settlement, the parties also agreed AstraZeneca would pay the consumers from nine states who had previously been excluded from the class. If the amount of submitted claims exceeded \$ 24 million, class members' recovery would be reduced proportionally.

6 In June 2007 some members of Classes 2 and 3 of the Track One plaintiffs proceeded to a bench trial against four defendants, including AstraZeneca, and the district court ruled in favor of the plaintiffs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 29-32 (D. Mass. 2007) (*In re Pharm. Trial*).

AstraZeneca also promised to pay all costs of distributing this money as well as \$ 8.7 million in attorneys' fees and costs, representing about one-third of the settlement [*10] amount. The parties agreed AstraZeneca would pay fees and costs separately and not deduct that from the class members' \$ 24 million recovery.

The parties expected a large portion of the total sum AstraZeneca was willing to pay would go unclaimed. Because Zoladex is used to treat prostate cancer, many class members were elderly, had died, or could die soon, and not all of them could be found. The parties addressed this issue through two mechanisms.

First, rather than paying the money up front into a fund that would distribute money to class members, AstraZeneca agreed to pay class members only on a comparatively easy claims-made basis. Class members only had to submit relatively minimal proof of when they took Zoladex. Then, based on a formula created by the plaintiffs' expert, class members would receive compensation for *double* their actual losses. Because the formula tried to calculate actual losses, it calculated the damages of class members who had supplemental insurance were 20 percent of their 20 percent Medicare co-payment, based on the average Medigap coverage that class members had.

Second, the parties agreed to create a fund, called a cy pres fund, that would pay any amount remaining [*11] (after payout to the claimants) of the \$ 24 million to "mutually acceptable charitable organizations funding cancer research or patient care" that the court would approve in the future. The parties capped the cy pres amount at \$ 10 million if not all of the \$ 24 million was paid out.

The parties submitted this agreement to the district court for preliminary approval on May 21, 2007. Howe quickly objected to the proposed settlement. She then raised six concerns but did not repeat all of them later in the settlement process. Those concerns were (1) the settlement changed the composition of the class, (2) the settlement compensated members on a claims-made basis rather than sending class members a check for their share of the class's damages, (3) the cy pres fund unfairly deprived class members of recovery, (4) the loss formula should not have reduced payments to those with supplemental insurance and also failed to calculate different coverage levels among those with supplemental insurance, (5) the settlement exposed class members to having other classes subrogate their claims, and (6) the settlement was tainted because the parties negotiated it and attorneys' fees simultaneously.

The district [*12] court granted preliminary approval of the settlement. *In re Pharm. Indus. Average Wholesale Price Litig.*, 520 F. Supp. 2d 267 (D. Mass.

2007) (order preliminarily approving settlement) (*In re Pharm. Preliminary Settlement Approval*). In the preliminary approval the court certified an expanded class that included the residents in nine states who were previously excluded, finding the class satisfied all requirements in *Rules 23(a) and (b)(3)*. [slip op.] at 2-4. The court again certified class counsel under *Rule 23(g)*. [slip op.] at 4.

In 2008 the parties sought final approval of the proposed settlement. The morning of the fairness hearing, May 1, 2008, Howe filed a reply brief objecting to the settlement. She again argued that class members, not a cy pres fund, should receive the entire settlement amount; the claims-made process and loss formula were flawed; and the settlement risked subrogation of the plaintiffs' claims. Howe proposed adopting the settlement distribution method used in one Track Two settlement. She argued AstraZeneca should use a Center for Medicare and Medicaid Services (CMS) database containing information about Medicare reimbursements to mail all class members [*13] a check for their equal share of the total amount class members overpaid, regardless of whether they had supplemental insurance. She also contended the attorneys' fees were excessive.

Although Howe's reply brief was tardy and its arguments were arguably waived, the district court considered each objection at the fairness hearing.⁷ The court found \$ 24 million was a reasonable settlement. Class counsel reported that they expected \$ 14 million of the \$ 24 million settlement to go unclaimed. Under the proposed settlement, up to \$ 10 million of those leftover funds would be distributed through cy pres. The district judge agreed with Howe that more money should go to the plaintiffs rather than to the cy pres fund. She instructed the parties that the settlement should pay *treble* damages to those plaintiffs who had the strongest claims because they obtained Zoladex in the "heartland period"⁸ and should correspondingly reduce the cy pres fund.

⁷ Howe had earlier filed an objection to the settlement that essentially cited, for three pages, Howe's earlier pleadings before the court without stating any specific grounds for the objection. During the fairness hearing, the district court properly [*14] held that anything raised in this pleading that Howe did not explain in the reply brief was waived. *See TAG/ICIB Servs. Inc. v. Sedeco Servicio de Descuento en Compras*, 570

F.3d 60, 66 n.6 (1st Cir. 2009) (holding an argument waived in part because the party failed to develop it in the district court).

8 The "heartland period," which the district court set as between December 1997 and 2003, was the time when plaintiffs who have the strongest claim took the subject drugs. *See In re Pharm. Trial, 491 F. Supp. 2d at 31-32.* The court found statutes of limitations barred claims before 1997 and the AWP scheme after 2003 was not as egregious because Congress changed the Medicare reimbursement policy. *Id.*

The court reserved deciding the attorneys' fees issue and rejected Howe's other arguments. The district judge agreed with class counsel that no subrogation issue existed. The court additionally accepted class counsel's justification for calculating damages for class members with supplemental insurance based on the average Medigap coverage, even if some members' insurance covered less than 80 percent of the Medicare co-payment. Class counsel reported that Howe's attorney had identified no plaintiff [*15] other than Howe who had different supplemental coverage, the plaintiffs' expert had reaffirmed that 80 percent coverage fairly approximated the class's supplemental insurance, and those few with different coverage would still be compensated beyond their losses.

Class counsel also explained, and the district court accepted, why Howe's proposal to mail equal checks to all class members was inappropriate. First, the CMS database did not reveal whether individuals had supplemental insurance. Because those with full supplemental insurance were excluded from the class, Howe's method would have the detriments of compensating non-class members, overcompensating those with supplemental insurance, and undercompensating those without it. By failing to consider individual damages, Howe's approach actually would dramatically reduce individual payouts.⁹ Second, unlike in this Track One case, it was prohibitively difficult for the parties in the Track Two settlement to calculate plaintiffs' individual damages. Those cases involved many drugs that people took at a variety of dosages over varying periods. Zoladex, by contrast, is taken at regular dosages at regular intervals. With information about [*16] when a plaintiff started Zoladex and whether the plaintiff had supplemental insurance, it was easy to calculate a Zoladex plaintiff's actual

damages.

9 The plaintiffs estimated that, under Howe's proposed method, class members would get just under \$ 54 each, well short of the hundreds or thousands of dollars some are entitled to under the settlement the district court ultimately approved.

The parties amended the proposed settlement agreement to address the court's instruction to increase the payout to class members. The amended agreement continued to provide that all class members would receive double their damages. But the new agreement no longer simply gave leftover money to charity. After all claimants were paid double damages, all heartland plaintiffs would receive *treble* damages pro rata. Then leftover money would be paid to charity through *cy pres*. Like the original *cy pres* payout, the parties capped the additional *treble* damages and *cy pres* distribution at \$ 10 million.

On October 2, 2008, the district court approved the amended settlement, subject to two further qualifications. *In re Pharm. Indus. Average Wholesale Price Litig., MDL No. 1456, Civ. A. No. 01-12257, 2008 U.S. Dist. LEXIS 111835 (D. Mass. Oct. 2, 2008)* [*17] (order partially approving settlement) (*In re Pharm. Partial Settlement Approval*). First, the court instructed the parties to adjust the settlement to pay heartland plaintiffs *treble* damages, then, if money remained, to pay *treble* damages to all class members pro rata. If money was still left over, the parties agreed the remaining money would be distributed to charity through *cy pres*. *2008 U.S. Dist. LEXIS 111835 at *76.* Second, it reduced the attorneys' fees to 30 percent of the recovery. *2008 U.S. Dist. LEXIS 111835 at *76-*77.* The district court discussed and rejected Howe's other concerns. *2008 U.S. Dist. LEXIS 111835 at *78-*79.*

The parties once more amended the settlement agreement to reflect the court's instructions. They again limited the total payout of *treble* damages to all class members and remaining money to charity through *cy pres* to \$ 10 million. The plaintiffs' expert predicted in February 2009 that, even with class-wide *treble* damages, class members would claim only about \$ 17.2 million, leaving about \$ 6.8 million of the \$ 24 million settlement left over for charity.

It is this amended settlement that the district court approved on December 15, 2008, as a fair, adequate, and

reasonable product of "extensive arm's-length negotiations." *In re Pharm. Final Settlement Approval*, 2008 U.S. Dist. LEXIS 111818 at *78 [*18]. Incorporating its prior orders dated August 16, 2005, and January 30, 2006, the district court found the settlement class satisfied the requirements of *Rules 23(a)* and *(b)(3)*. 2008 U.S. Dist. LEXIS 111818 at *75-*76.

The court again addressed Howe's objections and rejected them. It found Howe's proposal that class members should all receive a check rather than submit a claim was unreasonable because that approach would ultimately reduce the amount all class members received. 2008 U.S. Dist. LEXIS 111818 at *80. The court also rejected Howe's contention that the damages formula unfairly reduced recovery for class members with supplemental insurance. The reduction in the settlement better reflected class members' real damages, and all members would receive more than their losses regardless. 2008 U.S. Dist. LEXIS 111818 at *80-*81. The court similarly held Howe's argument that the formula unfairly calculated all supplemental-insurance reductions based on the 80 percent average supplemental coverage rather than based on individuals' insurance policies was meritless because the number of affected class members was small and because those with less coverage would receive more than their damages. 2008 U.S. Dist. LEXIS 111818 at *81. [*19] The district court rejected Howe's other objections. *Id.*

Howe now appeals the court order approving the settlement agreement.

II.

We review the district court's approval of a settlement for abuse of discretion. *City P'ship Co. v. Atl. Acquisition Ltd. P'ship*, 100 F.3d 1041, 1043 (1st Cir. 1996). We review any legal conclusions de novo. *McKenna*, 475 F.3d 418, 422 (1st Cir. 2007).

In turn, "[a] district court can approve a class action settlement only if it is fair, adequate and reasonable," *City P'ship*, 100 F.3d at 1043, "or (in shorthand) 'reasonable,'" *Nat'l Ass'n of Chain Drug Stores*, 582 F.3d at 44. If the parties negotiated at arm's length and conducted sufficient discovery, the district court must presume the settlement is reasonable. *City P'ship*, 100 F.3d at 1043. "[T]he district court enjoys considerable range in approving or disapproving a class settlement, given the generality of the standard and the need to balance [a

settlement's] benefits and costs." *Nat'l Ass'n of Chain Drug Stores*, 582 F.3d at 45.

On appeal Howe argues the settlement is unreasonable because it creates a cy pres fund, the agreement's claims process and formula for calculating loss are inappropriate, and the [*20] parties allegedly discussed settlement and attorneys' fees together. Howe also claims that the court's final approval order did not satisfy the requirements of *Rule 23(c)(1)(B)* to define the expanded class and its claims and that the court did not properly certify class counsel under *Rule 23(g)* when approving the settlement. The district court did not abuse its discretion by rejecting these arguments.

A. The District Court Did Not Abuse Its Discretion by Finding the Settlement Provision Creating a Cy Pres Fund Was Fair, Adequate, and Reasonable

Appellate courts review a district court's conclusion that a settlement agreeing to a cy pres distribution is reasonable for abuse of discretion. *E.g., In re Airline Ticket Comm'n Antitrust Litig.*, 307 F.3d 679, 682 (8th Cir. 2002); *Wilson v. Sw. Airlines*, 880 F.2d 807, 811 (5th Cir. 1989). Howe raises two challenges to the cy pres distribution in this settlement: that the class members are entitled to any surplus settlement money and that class counsel had a conflict of interest when negotiating the cy pres distribution. We find no abuse of discretion.

1. The Cy Pres Distribution

This circuit has not had occasion to consider whether settlement [*21] agreements in class actions may establish cy pres funds. Other circuits have approved agreements that provide for cy pres funds, particularly those negotiated at arm's-length by the parties. See A. Conte & H.B. Newberg, 4 *Newberg on Class Action* § 11:20, at 28-31 (4th ed. 2002).

A cy pres¹⁰ distribution results from application of a legal doctrine that courts have imported into class actions from trusts and estates law. In trusts and estates law, cy pres, taken from the Norman French expression *cy pres comme possible* ("as near as possible"), "save[s] testamentary gifts that otherwise would fail" because their intended use is no longer possible. *In re Airline Ticket Comm'n*, 307 F.3d at 682. Courts permit the gift to be used for another purpose as close as possible to the gift's intended purpose. *Id.*

10 Some courts and commentators have used the terms "cy pres" and "fluid recovery" interchangeably. *E.g., Mirfasihi v. Fleet Mortgage Corp.*, 356 F.3d 781, 784 (7th Cir. 2004); *Molski v. Gleich*, 318 F.3d 937, 954 (9th Cir. 2003); *Democratic Cent. Comm. of D.C. v. Washington Metro. Area Transit Comm'n*, 84 F.3d 451, 455, 318 U.S. App. D.C. 11 (D.C. Cir. 1996); 4 Conte & Newberg, *supra*, § 11:20, at 28. These terms may [*22] be different. *See* 3 Conte & Newberg, *supra*, § 10:17, at 517 & n.7. Here we simply use "cy pres."

In class actions, courts have approved creating cy pres funds, to be used for a charitable purpose related to the class plaintiffs' injury, when it is difficult for all class members to receive individual shares of the recovery and, as a result, some or all of the recovery remains. *Id.*; 4 Conte & Newberg, *supra*, § 11:20. The use of a cy pres fund sometimes "prevent[s] the defendant from walking away from the litigation" without paying a full recovery because of practical obstacles to individual distribution. *Mirfasihi v. Fleet Mortgage Corp.*, 356 F.3d 781, 784 (7th Cir. 2004); *see also* 3 Conte & Newberg, *supra*, § 10:15, at 513 ("[T]he cy pres . . . distributions serve the objectives of compensation for the class (albeit in an indirect manner), access to judicial relief for small claims, and deterrence of illegal behavior.").

Court-mandated cy pres distributions, as opposed to court-approved settlements using cy pres, are controversial. *See Democratic Cent. Comm. of D.C. v. Washington Metro. Area Transit Comm'n*, 84 F.3d 451, 455 n.2, 318 U.S. App. D.C. 11 (D.C. Cir. 1996); 3 Conte & Newberg, *supra*, §§ 10:20-24, [*23] at 529-39; 4 *id.* § 11:20, at 28. But "courts are not in disagreement that cy pres distributions are proper in connection with a class settlement, subject to court approval of the particular application of the funds." 4 Conte & Newberg, *supra*, § 11:20, at 28. Because this case involves a settlement, we need not reach the questions raised by court-created cy pres funds.

Courts have approved cy pres funds in settlements in at least two circumstances. *Id.* First, cy pres settlement funds have been approved when it is economically infeasible to distribute money to class members. *Id.*; *see, e.g., Mirfasihi*, 356 F.3d at 784 (rejecting a settlement because it was feasible to compensate class members individually); *Molski v. Gleich*, 318 F.3d 937, 954-55

(9th Cir. 2003) (same). Distribution of all funds to the class can be infeasible, for example, when class members cannot be identified, when the class changes constantly, or when class members' individual damages--although substantial in the aggregate--are too small to justify the expense of sending recovery to individuals. *Mirfasihi*, 356 F.3d at 784; *Powell v. Ga.-Pac. Corp.*, 119 F.3d 703, 706 (8th Cir. 1997); 3 Conte & Newberg, *supra*, § 10:16, [*24] at 513 n.1. In these cases, some courts have permitted the parties to create a cy pres fund *in lieu of* a class payout. *See Mirfasihi*, 356 F.3d at 784. That is not our situation.

Second, courts have allowed parties to establish cy pres funds when money remained from the defendant's payout after money for damages had been distributed to class members. *In re Airline Ticket*, 307 F.3d at 684. This situation often arises because some class members never claimed their share. *Six (6) Mexican Workers v. Ariz. Citrus Growers*, 904 F.2d 1301, 1307 (9th Cir. 1990). Among other solutions, courts have approved giving money unclaimed after payout to class members to charities related to the plaintiffs' injuries. *Id.*; *e.g., In re Simon II Litig.*, 407 F.3d 125, 131 (3d Cir. 2005); *In re Mexico Money Transfer Litig.*, 267 F.3d 743, 746 (7th Cir. 2001); *Powell*, 119 F.3d at 706-07 (8th Cir. 1997); *Six (6) Mexican Workers*, 904 F.2d at 1307. This kind of cy pres fund is at issue in this case.

The settlement provision creating a cy pres fund here is somewhat unusual in its timing. Under the final settlement, all class members will receive treble damages before any money goes to cy pres. The parties already know [*25] that some original class members will not file claims because they are elderly or have died and their heirs will not stand in their shoes. They expect a significant amount of the \$ 24 million will go unclaimed, and that expectation is supported by expert evidence predicting that class members will claim only about \$ 17.2 million, leaving approximately \$ 6.8 million left over. The parties have agreed that any remainder will go, after distribution of treble damages to class members, to cancer or patient-related charities.

Although unusually timed, the cy pres fund in this case, contrary to Howe's argument, is not taking damages away from the class members. The settlement permits all plaintiffs to claim and be paid their damages--indeed *treble* their damages--before any money is paid to charity through cy pres. This process is like other, routinely

approved cy pres distributions. *See, e.g., Powell, 119 F.3d at 705-06* (refusing, after money in a settlement fund remained, to distribute the rest to class members because "neither party ha[d] a legal right" to the unclaimed funds); *In re Folding Carton Antitrust Litig.*, 744 F.2d 1252, 1253-54 (7th Cir. 1984) (holding a cy pres distribution was [*26] appropriate when \$ 6 million remained in a fund created to pay costs and extra claims in a settlement because "neither the plaintiff class nor the settling defendants ha[d] any right" to the money). It would elevate form over substance to require the parties to wait until after all claims are paid before reaching an agreement as to how to distribute any remaining money to charity.

Howe nevertheless insists that the class members are entitled to receive any remaining money. She argues that, when deciding how to allocate remaining money, the primary consideration is whether it is economically infeasible to distribute the remaining proceeds to all claimants. Howe relies on and, in our view, Howe misunderstands the American Law Institute's ("ALI") recent draft of the Principles of the Law of Aggregate Litigation discussing the appropriateness of cy pres distributions in settlements. *See American Law Institute, Principles of the Law of Aggregate Litigation* § 3.07 (Apr. 1, 2009) (proposed final draft) [hereinafter "ALI Aggregate Litigation Draft"].¹¹ The question before us is not whether the settlement complies with the ALI draft, but whether the district court abused its discretion in approving [*27] the cy pres part of the settlement. *Cf. Bobby v. Van Hook*, 130 S. Ct. 13, 175 L. Ed. 2d 255, 2009 WL 3712013, at *3 (2009) (noting, in a criminal appeal arguing that the defendant's counsel was ineffective, that "'American Bar Association standards and the like' are 'only guides' to what reasonableness means" (quoting *Strickland v. Washington*, 466 U.S. 668, 688, 104 S. Ct. 2052, 80 L. Ed. 2d 674 (1984))) (per curiam).

¹¹ Howe cites one district court case relying on the ALI proposed draft. But that court used the draft's reasoning to approve a settlement, not reject a settlement. *In re Tyco Int'l Multidistrict Litig.*, 535 F. Supp. 2d 249, 262 (D.N.H. 2007).

The district court's actions in this case were entirely congruent with the proposed draft's purposes. The ALI's proposed draft expresses a policy preference, when settlement money remains, for redistributing that money

to class members to ensure they recover their losses. The ALI was concerned that cy pres funds are often inappropriate because "few settlements award 100 percent of a class member's losses, and thus it is unlikely in most cases that further distributions to class members would result in more than 100 percent recovery." ALI Aggregate Litigation Draft § 3.07 cmt. [*28] b. The ALI also believed "that in most circumstances distributions to class members better approximate the goals of the substantive laws than distributions to third parties that were not directly injured by the defendant's conduct." *Id.*

The district court shared these concerns. The court ultimately insisted that the settlement pay class members treble damages before any money is distributed through cy pres. This set the benchmark well above the ALI's hope that class members might receive 100 percent recovery.

And the court recognized that the cy pres fund serves the goals of civil damages by ensuring AstraZeneca fairly pays for the class's alleged losses. We asked at oral argument why AstraZeneca would be willing to pay a total sum more than the treble damages for each class member. Counsel for Plaintiff Townsend replied that the plaintiffs had insisted on AstraZeneca paying a larger sum to better represent the losses of the entire class, including those class members who would never claim their recovery.

The district court's approval reflected another important concern: facilitating a settlement in a hard-fought, complex class action. *See Durrett v. Housing Auth.*, 896 F.2d 600, 604 (1st Cir. 1990) [*29] (recognizing a policy encouraging class action settlements). Achieving settlement in such cases is not easy. District judges must realistically evaluate settlements based on the circumstances of the case. "[T]he ultimate decision by the judge involves balancing the advantages and disadvantages of the proposed settlement as against the consequences of going to trial or other possible but perhaps unattainable variations on the proffered settlement." *Nat'l Ass'n of Chain Drug Stores*, 582 F.3d at 44. The court's judgment here was not an abuse of discretion.

2. Conflict of Interest

As we read her argument, Howe also objects that the district court abused its discretion by finding the settlement was reasonable even though class counsel

allegedly had a conflict of interest. We have not before considered what effect potential conflicts of interest by attorneys have on class settlements. Although they have substantial discretion to approve settlements, district judges do have responsibility to monitor class counsel's performance.¹² "Because class actions are rife with potential conflicts of interests between class counsel and class members, district judges are expected to give careful scrutiny [*30] to the terms of the proposed settlements in order to make sure that class counsel are behaving as honest fiduciaries for the class as a whole." *Mirfasihi*, 356 F.3d at 785 (citations omitted) (collecting cases).

12 When reviewing settlements, district courts also must ensure class counsel have met their ongoing duty, imposed by Rule 23(g)(4), to fairly and adequately represent the class. *See Key v. Gillette Co.*, 782 F.2d 5, 7 (1st Cir. 1986). The duty of adequate representation requires counsel to represent the class competently and vigorously and without conflicts of interest with the class. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 626 n.20, 117 S. Ct. 2231, 138 L. Ed. 2d 689 (1997); *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1020 (9th Cir. 1998); *Rutherford v. City of Cleveland*, 137 F.3d 905, 909 (6th Cir. 1998); *Andrews v. Bechtel Power Corp.*, 780 F.2d 124, 130 (1st Cir. 1985); *see also* 1 Conte & Newberg, *supra*, § 3:22. The duty to avoid conflicts is serious. Class counsel are fiduciaries to the class. *Rodriguez v. W. Publishing Corp.*, 563 F.3d 948, 968 (9th Cir. 2009); *see also* *Sondel v. Nw. Airlines, Inc.*, 56 F.3d 934, 938 (8th Cir. 1995); 1 Conte & Newberg, *supra*, § 3:40, at 520 & n.5.

Howe alleges class counsel [*31] had a conflict of interest with the class because some attorneys had previously represented Prescription Action Litigation (PAL), an organization dedicated to reducing costs of pharmaceuticals in part by bringing class actions challenging industry practices. Howe argues that loyalty to the class obligated class counsel to demand the highest possible payout to class members. Counsel's affiliation with PAL, she contends, instead caused the attorneys to push for a cy pres fund because PAL's express purpose is to create cy pres funds and because counsel intended to distribute the fund's proceeds to PAL.

We reject Howe's description of counsel's

obligations, PAL's purposes, and the settlement's terms. As we have explained, there was nothing inherently wrong with class counsel advocating for a cy pres fund to benefit those class members whose recovery would go unclaimed after counsel ensured all claimants would receive more than their damages. Howe presents no evidence that PAL's purpose is to promote cy pres distributions, and the record is otherwise. PAL cannot receive any cy pres funds from this settlement. The settlement provides the cy pres money will go to "mutually acceptable charitable [*32] organizations funding cancer research or patient care," a description PAL does not meet.

B. The District Court Did Not Abuse Its Discretion by Approving the Settlement's Method for Calculating Class Members' Damages and Distributing the Settlement Amount

Howe raises three objections on appeal to the district court's approval of the method for calculating and distributing class members' individual recovery. First, Howe argues in one sentence that the district court should not have approved the settlement because it reduced class members' payments if they had supplemental insurance. This argument is waived because Howe has failed to develop it on appeal. *See United States v. DeCologero*, 530 F.3d 36, 60 (1st Cir. 2008).

Even were it not waived, the argument has no merit. The settlement formula tailors class members' recovery to their actual losses, since those who had supplemental insurance paid less out of pocket than those who did not. 13 As the district court found, this agreement therefore avoids undercompensating class members who lacked supplemental insurance. *See In re Pharm. Final Settlement Approval*, 2008 U.S. Dist. LEXIS 111818 at *79; *In re Pharm. Partial Settlement Approval*, 2008 U.S. Dist. LEXIS 111835 at *79. [*33] And by limiting those with supplemental insurance to their actual co-payment, the settlement makes more money available to more class members. *See In re Pharm. Final Settlement Approval*, 2008 U.S. Dist. LEXIS 111818 at *79.

13 As the plaintiffs explained to the district court, these insurers are members of another class against these defendants.

Second, Howe asserts that the settlement should pay class members with supplemental insurance according to their individual coverage. Howe's insurance covered 50

percent of her Medicare co-pay, not 80 percent as the loss formula assumes, and she wants her share adjusted. The district court rejected this argument because Howe and any similar class members, at double or treble damages, would still receive well above their damages. *2008 U.S. Dist. LEXIS 111818 at *81.*

That conclusion was not an abuse of discretion. Howe was the only plaintiff known to counsel (and the court) who had different coverage. The plaintiffs' expert had reaffirmed his formula was appropriate despite Howe's objection. And all class members, even if others existed who, like Howe, had less supplemental coverage, would [*34] receive more than their actual damages.¹⁴

14 The plaintiffs estimate Howe will receive about \$ 200 more than her actual losses.

Third, Howe again advocates a distribution system like the one in a Track Two settlement. She argues all class members should simply receive a check representing their share of the total losses reported in the CMS database.

The district court could determine this plan was not more equitable than the distribution method in the settlement. Because the CMS database does not show who had supplemental insurance, this system would ultimately reduce class members' payouts. It would compensate nonmembers and overcompensate class members who had supplemental insurance. The district court understood that, unlike in Track Two, it was possible to avoid this problem in this case because the parties could calculate Zoladex patients' losses.

C. Howe's Objection to Class Counsel Allegedly Negotiating Attorneys' Fees with the Settlement Is Waived

Howe contends the settlement agreement is "tainted" because the parties negotiated the settlement and attorneys' fees together. Class counsel argue they did not. Howe raised this objection when the district court was considering granting [*35] preliminary but not final approval to the settlement. She therefore waived it. *See Iverson v. City of Boston, 452 F.3d 94, 102 (1st Cir. 2006).*

D. The District Court Satisfied the Requirements of Rule 23(c)(1)(B)

The meaning of *Rule 23(c)* is a legal question we interpret de novo. *See NEPSK, Inc. v. Town of Houlton, 283 F.3d 1, 5 (1st Cir. 2002)* (interpreting a federal rule of procedure de novo).

Howe objects to the court's certification order under *Rule 23(c)(1)(B)*. She presents this argument for the first time on appeal, and it is therefore waived. *See In re New Motor Vehicles Canadian Exp. Antitrust Litig., 533 F.3d 1, 6 (1st Cir. 2008)*. Nevertheless, we address this issue in order to provide guidance to courts interpreting and applying this rule.

Rule 23(c)(1)(B), which was added in 2003, requires orders certifying classes to "define the class and the class claims, issues, or defenses."¹⁵ *Fed. R. Civ. P. 23(c)(1)(B)*. The advisory notes do not clarify the rule further. This court has not before addressed the meaning of *23(c)(1)(B)*. Only the Third Circuit has interpreted it. *Wachtel ex rel. Jesse v. Guardian Life Ins. Co. of Am., 453 F.3d 179, 184-88 (3d Cir. 2006)*.

15 Orders also must [*36] "appoint class counsel under *Rule 23(g)*." *Fed. R. Civ. P. 23(c)(1)(B)*. We address Howe's objections to class counsel appointment below.

Howe's arguments assume that *Rule 23(c)(1)(B)* applies to amended certification orders. As we read her brief, Howe solely objects that the district court's December 15, 2008, order did not meet her reading of *Rule 23(c)(1)(B)*. That order certified the final settlement class, which was expanded to include the residents from nine states who were previously excluded, and finally approved the settlement agreement. *In re Pharm. Final Settlement Approval*, MDL No. 1456, Civ. A. No. 01-12257. Howe contends the district court could not satisfy *Rule 23(c)(1)(B)* by incorporating by reference, as it did, its prior orders issued on August 16, 2005, and January 30, 2006, certifying the original class. *2008 U.S. Dist. LEXIS 111818 at *75*. She says the court's December 2008 certification order had to exhaustively explain and justify the certification decision for the expanded class.

Howe's brief presents three arguments why the December 2008 order erred under *Rule 23(c)(1)(B)*. First, by incorporating its prior orders and not giving a full restatement of those orders, Howe argues, the district [*37] court did not define the class or its claims in sufficient detail. Second, even if the district court could

incorporate prior orders, Howe contends that the August 2005 order, which discussed whether to certify the original class, did not define the class claims, issues, or defenses with sufficient clarity. Third, Howe argues, neither the December 2008 order nor the prior orders explained why the court approved the expanded settlement class.

We begin with the rule's plain text as well as its structure and purpose. *See Pavelic & LeFlore v. Marvel Entm't Group*, 493 U.S. 120, 123, 110 S. Ct. 456, 107 L. Ed. 2d 438 (1989) (giving "the Federal Rules of Civil Procedure their plain meaning"); *cf. Simmons v. Galvin*, 575 F.3d 24, 35 (1st Cir. 2009) (explaining that we interpret statutes according to "the language itself, the specific context in which that language is used, and the broader context of the statute as a whole" (quoting *Nken v. Holder*, 129 S. Ct. 1749, 1756, 173 L. Ed. 2d 550 (2009)) (internal quotation marks omitted)). To resolve any ambiguities, we may also consider the rule's drafting history. *Cf. Bercovitch v. Baldwin Sch., Inc.*, 133 F.3d 141, 149 (1st Cir. 1998) ("[C]ourts look first to the text of a statute, and then to the legislative [*38] history if the meaning of the text is ambiguous.").

Rule 23(c)(1)(B) explains the contents of a certification order: the order must clarify and detail the identity of a class and the class claims, issues, or defenses in a class action. *See Merriam-Webster's Collegiate Dictionary* 303 (10th ed. 1993) (defining to "define" as "to make distinct, clear, or detailed"); *see also Wachtel*, 453 F.3d at 185. *Rule 23(c)(1)* contains two other provisions governing class certification orders. First, "[a]n early practicable time after a person sues or is sued as a class representative, the court must determine by order whether to certify the action as a class action." *Fed. R. Civ. P. 23(c)(1)(A)*. And "[a]n order that grants or denies class certification may be altered or amended before final judgment." *Fed. R. Civ. P. 23(c)(1)(C)*. The federal rules contemplate district courts issuing an order certifying a class and detailing the class composition and the case's issues and claims, an order the court can amend before final judgment.

Rule 23(c)(1) does not explain whether *23(c)(1)(B)*'s substantive requirements apply to amended orders issued under *23(c)(1)(C)*. But *Rule 23(c)(1)(B)*'s text appears to apply [*39] to any order certifying a class, including orders certifying an amended class. The rule governs "[a]n order that certifies a class action." *Fed. R. Civ. P.*

23(c)(1)(B). The text uses "an" rather than "the," which suggests the drafters did not mean to restrict *23(c)(1)(B)* to a single certification order in a case. Courts have interpreted similar language in *Rule 23(f)*, which applies to "an order granting or denying class-action certification," to permit interlocutory review of amended orders. *See Gutierrez v. Johnson & Johnson*, 523 F.3d 187, 199 n.12 (3d Cir. 2008); *Carpenter v. Boeing Co.*, 456 F.3d 1183, 1191 (10th Cir. 2006).

The text of *Rule 23(c)(1)* does not specify how courts can accomplish the rule's aims, but the rule is meant to serve certain functions. The depth of explanation courts should provide in amended certification orders depends on the circumstances. Courts can amend certification orders to reflect major changes or minor adjustments to the class. *See Fed. R. Civ. P. 23(c)(1)(C)*. District courts should ensure that, after the new order, the class's composition and claims remain well defined.

This interpretation makes sense in light of *Rule 23(c)(1)(B)*'s history and purpose. [*40] *Rule 23* was substantially revised in 2003 to "provide the district courts with the tools, authority, and discretion to closely supervise class-action litigation." *See Comm. on Rules of Practice and Procedure, Judicial Conference, Report of the Judicial Conference* 8 (Sept. 2002). As part of this project, the rules committee made several amendments to *Rule 23(c)* in 2003 that put greater emphasis on understanding and articulating the "contours" of the class action throughout the litigation. *Wachtel*, 453 F.3d at 186; *see also L. J. Hines, "Challenging the Issue Class Action End-Run,"* 52 Emory L.J. 709, 763 (2003) (noting the 2003 amendments' emphasis on defining a class's issues).

An amendment to *23(c)(1)(A)* adjusted the timing of class certification to give courts flexibility to wait to certify the class until the court feels it understands the case and the issues it raises.¹⁶ *Wachtel*, 453 F.3d at 186; *see also Fed. R. Civ. P. 23(c)(1)(A)* advisory comm. notes on 2003 amendments. *Rule 23(c)(2)(B)* was amended to make notice to class members more informative. It now requires notice to state "the definition of the class certified" and "the claims, issues, or defenses." *Fed. R. Civ. P. 23(c)(2)(B)(ii)-(iii)*. [*41] ¹⁷ *Rule 23(c)(1)(B)* was added, at least in part, to help appellate courts reviewing an order better understand the district court's decision. *See Comm. on Rules of Practice and Procedure, supra*, at 11. ¹⁸

16 The amendment was intended in part to address the "critical need" to "determine how the case will be tried." *Wachtel*, 453 F.3d at 186 (quoting *Fed. R. Civ. P.* 23(c)(1)(A) advisory comm. notes on 2003 amendments). The drafters observed that "[a]n increasing number of courts require a party requesting class certification to present a 'trial plan' that describes the issues likely to be presented at trial and tests whether they are susceptible to class-wide proof." *Id.* (internal quotation marks omitted).

17 The drafters intentionally made this language parallel with *Rule 23(c)(1)(B)*. *Fed. R. Civ. P.* 23(c)(1)(C) advisory comm. notes on 2003 amendments.

18 The drafting history says *Rule 23(c)(1)(B)* was added to assist interlocutory review of certification orders under *Rule 23(f)*. Comm. on Rules of Practice and Procedure, *supra*, at 11. Because appellate courts have discretion whether to permit interlocutory review under *23(f)*, however, appellate courts often do not review certification orders [*42] until after final judgment. *See Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 293-94 (1st Cir. 2000). *Rule 23(c)(1)(B)* does not limit itself to orders that will be reviewed on interlocutory appeal. One of its purposes seems to be to facilitate appellate review at any stage.

We see many possible benefits to the 2003 amendments to *Rule 23(c)*. Overall, better comprehension and explanation of the class and the class claims helps district courts, appellate courts, attorneys, and parties all proceed with more information and mutual understanding. *See Fed. R. Civ. P.* 23 advisory comm. notes on 2003 amendments; *see also Wachtel*, 453 F.3d at 186-87 (discussing the effect of the 2003 amendments); Comm. on Rules of Practice and Procedure, *supra*, at 9-12 (explaining the purpose of the 2003 amendments to *Rule 23(c)*).

In this case the district court satisfied *Rule 23(c)(1)(B)*'s text and purpose. The court could incorporate its prior orders by reference when certifying the expanded class. Looking at the incorporated orders, the August 2005 order plainly defined the class and the class claims, issues, and defenses in sufficient detail. The district court devoted many pages to the class's factual [*43] allegations against the defendant. *See In re Pharm.*

Preliminary Class Certification, 230 F.R.D. at 65-76. It then carefully analyzed the proposed class's suitability for certification, again explaining the issues common to the class. *See id.* at 77-85, 96. The court also discussed the state consumer protection statutes underlying the class's claim, noting differences among them. *Id.* at 83-85.

It is also perfectly clear why the district court expanded the settlement class in the December 2008 order.¹⁹ The court originally excluded residents in these nine states because the defendants had objected that including residents from these states defeated the predominance requirement, *see Fed. R. Civ. P.* 23(b)(3), since their consumer-protection statutes differed. *In re Pharm. Preliminary Class Certification*, 230 F.R.D. at 83-85; *In re Pharm. Class Certification*, 233 F.R.D. at 230. In the settlement, however, AstraZeneca bargained for "total peace" to resolve all remaining claims against it. When expanding the class, the December 2008 order references these prior orders and "the record before the Court." *In re Pharm. Final Settlement Approval*, 2008 U.S. Dist. LEXIS 111818 at *75. That is [*44] enough.

19 The rule says only that a court must define, not necessarily justify, a class and its claims. *See Fed. R. Civ. P.* 23(c)(1)(B).

E. Howe's Argument That the District Court Did Not Properly Certify Class Counsel under Rule 23(g) Is Waived

Rule 23(g) requires district courts to appoint class counsel and governs how courts should choose counsel. *Fed. R. Civ. P.* 23(g)(1)-(2). Howe argues the district court did not appoint class counsel under *Rule 23(g)* when approving the settlement in this case and that the district court did not satisfy *Rule 23(g)*'s requirements.

Howe is mistaken. The district court did find, while approving the settlement, that class counsel met *Rule 23(g)*'s requirements. *In re Pharm. Preliminary Settlement Approval*, 520 F. Supp. 2d 267, [slip op.] at 3-4; *In re Pharm. Final Settlement Approval*, 2008 U.S. Dist. LEXIS 111818 at *76.

Any argument the district court did not satisfy *Rule 23(g)* is waived because Howe raises this claim for the first time on appeal. *See Rocafort v. IBM Corp.*, 334 F.3d 115, 121 (1st Cir. 2003).

The approval of the settlement is *affirmed*.